REMARKS

Claims 1, 2, 4-6, 11-16, 21, 31, 32, 38-58 and 60-65 are pending herein. Claims _____ are canceled herein without prejudice. Claims _____ are amended herein to more particularly define the invention and are not narrowing amendments.. Support for these claim amendments is found throughout the specification as set forth below and in the original claim language. It is believed that no new matter is added by these amendments and their entry is respectfully requested. In light of these amendments and the following remarks, applicants respectfully request reconsideration of the pending application and allowance of the pending claims to issue.

I. Provisional double patenting rejections

A. Claims 1-41 and 58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1, 2, 5-13, 16, 17, 20-42 and 44-56 of copending application serial no. 09/876.360.

B. Claims 1, 3, 4, 6, 11, 31, 32, 38, 39, 50, 51, 54, 55 and 58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1, 2, 5, 13-16, 18-21, 23-31, 34, 36, 40, 41, 43-46 and 50 of copending application serial no. 09/876.503.

C. Claims 1, 2, 4-16, 21, 31, 32, 38-58, 62 and 63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-8, 11, 12, 17, 18, 20-24, 27-29, 33-74 and 84-92 of copending application serial no. 09/560,111.

[THESE ARE ALL PROVISIONAL REJECTIONS- WE CAN DISCUSS AT INTERVIEW]

II. Rejection under 35 U.S.C. § 112, second paragraph

A. The use of the term "vector" in claims 1, 12, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 62 and 64.

The term " vector" as recited in the claims and throughout applicants' specification is clear and definite in its meaning and it would be readily apparent to one of ordinary skill in the art that the silencing vector of the present invention can be a single vector, as that phrase is understood. In particular, it is pointed out throughout the specification that the silencing vector described therein can be a single construct as recited, for example, on page 8, lines 8-11 (describing that the present invention demonstrates the ability to silence endogenous gene expression systemically in a plant using a plant virus construct); on page 9, lines 13-17 and on page 10, lines 14-16 (describing monopartite geminiviruses, which have a single genomic component, as included among the geminiviruses of this invention); on page 17, lines 19-27, as well as in claims 33, 39, 52 and 90 (describing a single vector comprising, at a minimum, an origin of replication, DNA encoding proteins necessary for replication and heterologous DNA); on page 13, lines 16-20 (wherein the term "DNA silencing vector" is defined to be a DNA construct capable of replicating within a host cell and carrying a heterologous DNA sequence that is similar or identical to an endogenous plant gene or gene fragment); on page 16, lines 23-31 (describing transfecting a plant with an altered DNA A component simultaneously with the DNA B component or with a binary plasmid comprising the combination of A and B components and also describing transfection of plant cells with a recombinant geminivirus transfer vector, which when used in an embodiment wherein both the A and B components are used, each component can be introduced into a plant cell separately or together on a single DNA construct); and on page 21, lines 12-14 (describing a preferred embodiment wherein plants are inoculated with microprojectiles carrying a geminivirus construct that includes both the A and B DNA components).

Furthermore, Example 3 describes that bombardment of plants with the TGMV-A construct alone resulted in silencing that was not observed to be systemic and that

systemic silencing occurred when plants were bombarded with the TGMV-A construct in combination with the TGMV-B construct (page 35, lines 19-22).

Thus, it is clear that the specification describes the silencing vector of this invention as a single vector. As noted in the specification and in some of the Examples therein, in some embodiments, the silencing vector can be introduced into a plant in combination with a separate DNA-B component if systemic silencing is desired. However, as demonstrated herein, in other embodiments, systemic silencing, if desired, can be achieved by including the necessary proteins encoded on the DNA-B component in a single silencing vector that also comprises the other elements necessary to achieve silencing.

It is also apparent from the teachings of the specification that silencing can be achieved without proteins from the DNA-B component. For example, the specification states on page 17, lines 28-31, that "[e]pisomal silencing constructs that utilize portions of DNA plant virus genomes do not have to include the viral movement proteins to accomplish gene silencing. The present inventors have determined that the viral movement proteins are non-essential for episomally-mediated gene silencing."

Thus, in some embodiments of the present invention, the DNA-B component or the coding sequences for the movement proteins can be included as a separate plasmid or included on a vector with the silencing vector and in other embodiments, the DNA-B component or coding sequences for the movement proteins need not be present at all in order to carry out the silencing methods of the claimed invention.

For the reasons set forth above, applicants assert that the term "silencing vector" as presented in the claimed invention is clear and definite in its meaning and that this rejection has therefore been mooted and applicants respectfully request its withdrawal.

B. The use of the phrase "a promoter associated with said endogenous plant gene" in claim 4.

[WE CAN DISCUSS AT THE INTERVIEW]

C. The use of the term "modifies" in claims 11, 21 and 58.

The specification, on page 12, lines 18-24, states that gene silencing can result in an "altered phenotype," which includes alterations in, for example, such characteristics as color, height or other aspects of growth and/or biochemical features that can occur, for example, at the level of a plant cell, a plant tissue or a whole plant (see, e.g., page 13, lines 1-3). Thus, it would be readily apparent to one of skill in the art that modification of a plant phenotype by the silencing methods of this invention results in alteration of the characteristics as described in the specification. It would also be clear to the ordinary artisan that such modifications or "alterations" would include the presence of a trait, an absence of a trait and/or a quantitative difference in an already existing trait. Therefore, applicants assert that claims 11, 21 and 58 are clear and definite in their meaning in the recitation of the term "modifies" and that this rejection is therefore mooted. For these reasons, applicants respectfully request its withdrawal.

III. Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 2, 4-6, 11-16, 21, 31, 32, 38-58 and 62-65 are rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention.

As discussed during the personal interview on October 16, 2002 with Examiners Kaushal and Priebe, applicants believe that the specification as filed provides adequate written description of the claimed invention and that this rejection should be withdrawn. In particular, it is acknowledged in the June 26, 2002 Office Action on page 4 and stated on page 1104 in the guidelines for written description as published in volume 66 of the Federal Register on January 5, 2001 that possession may be shown by an actual reduction to practice of an invention. Applicants have

reduced to practice a geminivirus silencing vector comprising a geminivirus genome comprising the geminivirus AL1, AL2 and Al3 coding sequences and comprising a heterologous DNA comprising at least a fragment of a gene endogenous to a plant and having all of the additional elements as set forth in claim 1 of the present invention. Thus, applicants have met the requirements for written description of the claimed invention and applicants further note that both Examiners Kaushal and Priebe concurred with this conclusion during the personal interview. Therefore, applicants believe this rejection has been overcome and respectfully request its withdrawal and allowance of the pending claims to issue.

In further support of applicants' assertion that the claimed invention meets the written description requirements, applicants also draw the Examiner's attention to Example 18 on page 65 of the Revised Interim Written Description Guidelines Training Materials prepared by the USPTO. In Example 18, an expression vector comprising a nucleic acid that encodes a protein of interest is described in a method claim for producing a protein of interest. (The actual claim in the example reads as follows: 1. A method of producing a protein of interested comprising: obtaining Neurospora crassa mitochondria, transforming said mitochondria with an expression vector comprising a nucleic acid that encodes said protein of interest, expressing said protein in said mitochondria, and recovering said protein of interest.) In the analysis of this claim for written description, it is stated in the Training Materials that "...gene expression is essential to the function/operation of the claimed invention. A particular nucleic acid is not essential to the claimed invention."

The analysis of this method claim goes on to state that the claimed method is novel and unobvious, that the claim is drawn to a genus of methods that can be used for expressing protein and that there is actual reduction to practice of a single embodiment. On the basis of this analysis, it is stated in the Training Materials that the method claim of Example 18 is adequately described in accordance with the Written Description Guidelines.

Although the present claims recite both compositions and methods, the same analysis can be applied here as was applied to the method claim of Example 18. In particular, in the present invention, it is easily recognized that expression of the heterologous DNA sequence of the claimed geminivirus silencing vector is essential to the function/operation of the claimed invention and that a particular heterologous DNA sequence is not essential to the claimed invention. Further analysis of the claimed invention along the lines of the analysis set forth in example 18 reveals that 1) the claimed silencing vector is novel and unobvious, as demonstrated herein; 2) the claim is drawn to a genus of geminivirus silencing vectors; and 3) there is actual reduction to practice of not just a single embodiment, but several embodiments of the claimed invention. Thus, as was the outcome of the analysis in Example 18, it is clear that the same outcome is warranted upon similar analysis of the claimed invention in the present application- that the claimed invention is adequately described in accordance with the Written Description Guidelines.

For the reasons set forth above, as well as the reasons set forth in applicants' previous response to this rejection, it is clear that applicants have met the written description requirement of the claimed invention and that this rejection has been mooted. Therefore, applicants respectfully request its withdrawal and allowance of the pending claims to issue.

IV. Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 2, 4-6, 11-16, 21, 31, 32, 38-58 and 62-65 are rejected under 35 U.S.C. §112, first paragraph, as allegedly being enabling only for geminivirus silencing vectors comprising fragments that are at least 403 bp in size and from coding sequences.

Applicants respectfully traverse this rejection and assert that the invention as claimed is adequately enabled for the full scope of the pending claims. Specifically, as discussed at the personal interview with Examiners Kaushal and Priebe on October 16, 2002, applicants have demonstrated that the claimed silencing vectors function as claimed in studies employing a variety of geminivirus genomes, a variety of heterologous DNA sequences and a variety of plants. Applicants provide herein evidence of two different geminivirus vectors, 17 different heterologous DNA sequences and species from two different plant families in which the claimed invention has been demonstrated to function as described, in the form of a Declaration of Dr. Dominique Robertson under 37 C.F.R. § 1.132, a copy of which is attached hereto.

Although it is applicants' belief that the claims are written are adequately enabled over the full scope of the invention, to address any concerns that Examiner may have regarding the term "fragment," pending claims reciting this term are amended herein to recite that the fragment is of a size sufficient to induce silencing. Support for this amendment can be found throughout the specification and at least on page 14, lines 2-3. This amendment is provided merely for clarity to more particularly define the invention and is not a narrowing amendment.

For the reasons provided above, applicants believe that the invention is fully enabled commensurate with the claims and respectfully request that this rejection be withdrawn.

V. Rejection under 35 U.S.C. § 102(b)

Claims 42 and 46 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Hayes et al.

These claims are not anticipated by the Hayes et al. reference. Specifically, the Hayes et al. reference is alleged to inherently teach the silencing vectors of this

invention even though the Hayes et al. reference teaches nothing more than a vector for the introduction of a neomycin transgene into plants that do not already have a neomycin transgene. The Hayes et al. reference provides no teaching or suggestion to put a neomycin transgene into a plant that already contains a neomycin transgene, which is the premise of the presently claimed invention. Thus, the Hayes et al. reference does not inherently disclose the invention of claims 42 or 46.

Double matter

In particular, applicants wish to point out the legal standard for inherency, as set forth in section 2112 in the MPEP, wherein In re Robertson is cited as stating that "[t]o establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." (169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). (Emphasis added.) The MPEP also cites Ex parte Levy as stating that "[i[n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." (17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)). (Emphasis in original.) It is clear from these cases that in order for the standard for inherency to be properly cited in an anticipation rejection, the allegedly inherent characteristic must necessarily flow from the teachings of the cited art and such a determination must be supported by fact or technical reasoning.

it is –

MPEP 2112 new pg. if anything old doesn't make it a new product

But product itself is the same. The plant is not a part of the claimed vector.

In the present case, there is no teaching or suggestion in the Hayes et al. reference that the vectors described therein are introducing a neomycin gene into a plant into which a neomycin gene has already been introduced and functionally established and that the effect of such later introduction is silencing of the previously introduced neomycin gene. Thus, there is no evidence that the claimed silencing vectors necessarily flow from the teachings of the cited art and therefore the claims of this invention cannot be anticipated as inherent in the teachings of Hayes et al. For

these reasons, applicants believe this rejection has been overcome and respectfully request its withdrawal.

VI. Rejection under 35 U.S.C. § 103

Claims 1, 2, 4-6, 11-16, 21, 31, 32, 38-58 and 62-65 are rejected under 35 U.S.C. § 103 as allegedly obvious in view of Hayes et al. in combination with Metzlaff et al., Theologis et al., Meyer et al. and Koes et al.

The cited references, either alone or in any combination, fail to render the claimed methods obvious. In particular, applicants first wish to point out that the primary reference of this obviousness rejection, the Hayes et al. reference, is the reference relied upon in the rejection of pending claims 42 and 46 under 35 U.S.C. § 102(b) as anticipatory for its allegedly inherent teachings of the claimed invention. It is stated in the section 2141.02 of the MPEP, with a citation to In re Rijckaert, that "[o]bviousness cannot be predicated on what is not known at the time an invention was made, even if the inherency of a certain feature is later established." (9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir.1993). Thus, the use of the Hayes et al. reference for its allegedly inherent teachings as the primary basis for this obviousness rejection renders the rejection improper and applicants request that it be withdrawn for this reason.

The Examiner is encouraged to contact the undersigned directly if such contact will expedite the examination and allowance of the pending claims.

No fee is believed due. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,

Mary L. Miller

Registration No. 39,303

CERTIFICATE OF MAILING
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, Washington, DC 20231, on November 26, 2002.

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